

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF JERSEY**

**IN RE: INVOKANA (CANAGLIFLOZIN)  
PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2750**  
**Master Docket No. 3:16-md-2750**

**JUDGE BRIAN R. MARTINOTTI**  
**JUDGE LOIS H. GOODMAN**

**THIS DOCUMENT RELATES TO:**

**Smith v. Janssen Pharmaceuticals, Inc. et al.,  
Case No. 3:18-cv-09725**

## NOTICE OF ANSWER AND AFFIRMATIVE DEFENSES

Pursuant to Case Management Order No. 14, Defendants Janssen Pharmaceuticals, Inc. (“JPI”), Johnson & Johnson, Janssen Research & Development, LLC, and Janssen Ortho LLC hereby file this Notice of Answer and Affirmative Defenses.

Defendants deny generally each and every allegation set forth in Plaintiff's Complaint, and each and every alleged cause of action therein, and further deny that Plaintiff has sustained the injuries alleged by reason of any act, breach, or omission on the part of Defendants. Defendants reserve the right to later file an answer to specifically address Plaintiff's allegations.

## FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

## SECOND AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails for lack of personal jurisdiction with respect to some or all of the Defendants.

### **THIRD AFFIRMATIVE DEFENSE**

The claims against Defendants are barred, in whole or in part, by laches and/or the applicable statute of limitations and/or repose.

### **FOURTH AFFIRMATIVE DEFENSE**

The claims against Defendants are barred, in whole or in part, by waiver and/or estoppel.

### **FIFTH AFFIRMATIVE DEFENSE**

If Plaintiff sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Plaintiff's own negligence and fault and were not caused or contributed to in any manner, by any alleged fault, negligence, or breach of warranty of Defendants, their officers, agents, contractors, servants, employees, or others for whom it was responsible. Plaintiff's recovery should be diminished by that percentage of fault attributable to Plaintiff and/or persons or entities other than Defendants for those injuries allegedly sustained by Plaintiff upon which the damages complained of in this action are based. Thus, Defendants' liability, if any, is limited to its percentage of responsibility for the injuries of Plaintiff, if any, regardless of whether or not other persons or entities are named as co-defendants.

### **SIXTH AFFIRMATIVE DEFENSE**

If Plaintiff sustained damages as alleged in the Complaint, which is denied, said damages were caused solely by or contributed to by the acts and fault of third parties and were not caused or contributed to by any acts or fault of Defendants, their officers, agents, servants, employees, contractors, or others for whom they were responsible. Defendants will identify the other persons or entities that may have been responsible with as much particularity as is feasible as discovery progresses and in sufficient time to allow the Plaintiff to respond and/or file pleadings.

Thus, Plaintiff's claims should be barred or proportionately reduced by the intentional and/or negligent acts of such known or unknown third parties.

#### **SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff sustained damages as alleged in the Complaint, which is denied, Plaintiff has failed to mitigate his/her damages and any recovery is to be diminished by the degree of said failure to mitigate.

#### **EIGHTH AFFIRMATIVE DEFENSE**

At all times relevant hereto, the knowledge of Plaintiff's physicians and/or other medical care providers with respect to the possible risks and the opportunity to warn of the possible risks, was superior to that of JPI, and, therefore, if there was any duty to warn Plaintiff of the risks, it was the duty of said physicians and/or other medical care providers, not of JPI, and breach of that duty was an intervening and/or superseding cause of the injuries alleged by Plaintiff.

#### **NINTH AFFIRMATIVE DEFENSE**

The product referred to in the Complaint is a prescription medication available only upon the prescription and/or order of a licensed physician and/or surgeon and is not available to the general public. JPI provided information concerning warnings, precautions, and complications to those persons to whom the prescription medications were available. Thus, Plaintiff's claims are barred, in whole or in part, by the "learned intermediary" doctrine.

#### **TENTH AFFIRMATIVE DEFENSE**

Plaintiff and/or Plaintiff's physicians and/or medical care providers and/or other third parties may have modified, altered, and/or misused the JPI product(s) referred to in the Complaint, if any, so that such changes in any said products or materials proximately caused Plaintiff's injuries, loss, and damages, if any.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

If it is proven at the time of trial that Plaintiff came into contact with JPI's product, then any product manufactured for and/or sold and/or distributed by JPI which was or may have been furnished to Plaintiff and which he/she came into contact or may have come into contact with, was furnished with adequate and appropriate warnings.

#### **TWELFTH AFFIRMATIVE DEFENSE**

The benefits of JPI product(s) referred to in the Complaint outweigh the risk of danger and/or harm, if any, inherent in said product(s).

#### **THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's injuries, if any, were proximately caused by unforeseeable, independent, intervening, and/or superseding event(s) beyond the control, and unrelated to any conduct, of Defendants. Defendants' actions or omissions, if any, were superseded by the negligence and wrongful conduct of others.

#### **FOURTEENTH AFFIRMATIVE DEFENSE**

The injuries and damages of which Plaintiff complains were not caused by any product distributed by JPI, but were caused by some other product, process, occurrence, event, or service over which Defendants exercised no control or right of control.

#### **FIFTEENTH AFFIRMATIVE DEFENSE**

Federal statutes and regulations preempt all state law governing the product that is the subject of the Complaint, and said product was in compliance with federal law at all times relevant to Plaintiff's claims.

#### **SIXTEENTH AFFIRMATIVE DEFENSE**

The claims against Defendants are barred, in whole or in part, by the provisions of Comments “j” and “k” to Section 402 of the Restatement (Second) of Torts.

#### **SEVENTEENTH AFFIRMATIVE DEFENSE**

The claims against Defendants are barred by Sections 2, 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

#### **EIGHTEENTH AFFIRMATIVE DEFENSE**

Defendants are entitled to a set-off from any recovery against it to the extent each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources.

#### **NINETEENTH AFFIRMATIVE DEFENSE**

Any dangers associated with the use of the prescription medications that may have caused Plaintiff’s injuries, if any, were open and obvious, and Plaintiff is therefore barred from recovery.

#### **TWENTIETH AFFIRMATIVE DEFENSE**

Some or all of the injuries alleged in the Complaint were caused or aggravated by Plaintiff’s pre-existing medical condition(s) or exposure to other substances utilized throughout his/her lifetime, by Plaintiff’s unusual susceptibility to injury, and/or by his/her idiosyncratic reaction.

#### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

Any and all warnings or information pertaining to products designed, manufactured for, distributed, and/or sold by JPI were at all times relevant to the Complaint in conformity with governmental requirements.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Defendants state that there is no alternative design for the product that was capable of preventing Plaintiff's alleged injuries.

#### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the United States Food and Drug Administration. Accordingly, this action is barred by the doctrines of primary jurisdiction and preemption.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the doctrine of accord and satisfaction, release, and/or payment.

#### **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

All or some of Plaintiff's claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims for punitive damages are in contravention of Defendants' rights under each of the following constitutional provisions:

- a. the Commerce Clause of Article I, Section 8 of the United States Constitution;
- b. the Contracts Clause of Article I, Section 10 of the United States Constitution;

- c. the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution;
- d. the Supremacy Clause of Article VI of the United States Constitution;
- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution;
- h. the Right to Counsel of the Sixth Amendment of the United States Constitution;
- i. the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;
- j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;
- k. the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and
- l. similar or corresponding provisions of the Constitution of the state of New Jersey and/or the state of Plaintiff's residency.

#### **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Defendants are entitled to the protections and limitations afforded under the New Jersey Punitive Damages Act, N.J.S.A. §§ 2A:15-5.9, *et seq.* and the New Jersey Product Liability Act, N.J.S.A. §§ 2A:58C-1, *et seq.*

#### **TWENTY-NINTH AFFIRMATIVE DEFENSE**

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards that are set forth in *Philip Morris USA v. Williams*, 549

U.S. 346 (2007), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and similar state cases.

#### **THIRTIETH AFFIRMATIVE DEFENSE**

Because of the lack of clear standards, any imposition of punitive damages against Defendants would be unconstitutionally vague and/or overbroad.

#### **THIRTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

#### **THIRTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's alleged causes of action are barred, in whole or in part, by lack of defect under either the prudent manufacturer test or the consumer expectations test.

#### **THIRTY-THIRD AFFIRMATIVE DEFENSE**

Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of the state whose law is deemed to apply in this case.

#### **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Defendants hereby give notice that they intend to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and thus reserve the right to amend their Answer to assert such defenses.

#### **JURY DEMAND**

Defendants request a trial by jury on all issues so triable.

#### **DESIGNATION OF TRIAL COUNSEL**

Mollie F. Benedict and John Q. Lewis are hereby designated as trial counsel.



DATED: July 2, 2018

DRINKER BIDDLE & REATH LLP

By: /s/ Michael C. Zogby

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Inc., Johnson & Johnson, Janssen Research &  
Development, LLC, and Janssen Ortho LLC

**CERTIFICATE OF SERVICE**

I hereby certify that on July 2, 2018, a copy of the foregoing Answer was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

/s/ Jennifer G. Chawla

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